

by way of the externally ported hydraulic control interface of the microfluidic cartridge. Prior to transfer, the sample may be lysed by causing flow of a fluid lysis buffer into the sample carrier to lyse the sample. For example guanidinium isothiocyanate may be used as a lysis buffer to enable RNA to be extracted from the sample.

**[0043]** The at least one chamber of the microfluidic cartridge preferably comprises a nucleic acid isolation chamber. The nucleic acid isolation chamber preferably comprises a surface to which the target nucleic acid will attach. For example, the solid phase extraction chamber may be pre-loaded with solid phase particles, such as silica beads, having a surface treatment to which the target nucleic acid binds. Where the nucleic acid is attached in this manner, some or all of the remainder of the lysed sample and the lysis buffer itself may be washed away by a wash buffer. Thus, in such embodiments, the microfluidic cartridge preferably further comprises a waste chamber in fluidic connection with the nucleic acid isolation chamber, for storing such waste material washed away from the nucleic acid. Further, in such embodiments, after washing the nucleic acid is preferably eluted from the solid phase material by the introduction of a suitable elution buffer, for example TRIS.

**[0044]** The microfluidic cartridge preferably further comprises an amplification test chamber. In embodiments comprising a nucleic acid isolation chamber, the amplification test chamber is preferably in fluidic connection with the nucleic acid isolation chamber. The amplification chamber is preferably pre-equipped with a stirrer to mix the sample template with oligonucleotide primers or the like which may be introduced via port(s) of the microfluidic cartridge. Preferably, the stirrer is substantially transparent so as not to obstruct optical detection of test results. The stirrer may comprise at least one magnet to provide for magnetic control of the stirrer. In such embodiments the control platform preferably comprises a magnetic stirrer controller. The target sequence, if present, is then amplified to a level whereby the presence of the target sequence may be rapidly detected using one of a range of detection methods, such as turbidimetric detection, or fluorescence detection.

**[0045]** The microfluidic cartridge preferably further comprises a positive control amplification chamber, and preferably further comprises a negative control amplification chamber. Each such chamber is preferably provided with a respective stirrer.

**[0046]** The microfluidic cartridge is preferably formed of transparent material at least in the vicinity of the amplification test chamber, to enable optical detection of the result of the nucleic acid amplification process. The control platform may optically detect the result of the nucleic acid amplification process by monitoring an intensity of a light signal transmitted through the amplification test chamber, for example where turbidity in the amplification test chamber arises as a result of amplification of the target nucleic acid (a positive test). Additionally or alternatively the control platform may optically detect the result of the nucleic acid amplification process by monitoring for optical emissions at a first wavelength which arise as a result of excitation of a fluorophores in the amplification test chamber by light of a second wavelength, such fluorophores arising in the event of a positive test.

**[0047]** Thus, embodiments of the present invention provide for a microfluidic cartridge which enables nucleic acid amplification techniques to be performed in a sealed environment

to provide for containment of potentially hazardous biological samples and amplicons. Embodiments of the invention exploit fluidics techniques by applying fluid flows and aspiration conditions to the port(s) of the microfluidic cartridge.

**[0048]** The system preferably further comprises temperature control means to provide for suitable temperature conditions for the particular nucleic acid amplification process applied. In some embodiments, the microfluidic cartridge may comprise a printed circuit for resistive heating when a current is passed through the printed circuit. In such embodiments the control platform preferably comprises electrical contacts for applying a suitable current through the printed circuit of the microfluidic cartridge to produce the necessary temperature conditions within the amplification chamber. Such an arrangement is advantageous in maintaining control complexity within the control platform while providing a simple heating mechanism upon the microfluidic cartridge.

**[0049]** Additionally or alternatively, the microfluidic cartridge may comprise a heating chamber proximal to and fluidly separate from the amplification chamber, with accompanying ports to provide for circulation of heating fluid through the heating chamber. Such embodiments provide for the control platform to generate heating fluid at a suitable temperature and to circulate the heating fluid through the heating chamber of the microfluidic cartridge. Heat from the heating fluid may be conducted to the amplification chamber to thus control a temperature of the amplification chamber. Temperature sensors may be mounted upon the microfluidic cartridge to provide temperature feedback to the control platform to control the temperature of the heating fluid.

**[0050]** The amplification process may be an isothermal amplification process. Use of an isothermal amplification process may be advantageous in simplifying temperature control requirements of the system. A particularly applicable isothermal amplification process may be the LAMP process (Loop-mediated Isothermal Amplification) manufactured by Eiken Chemical Co., of Tokyo, Japan. Additionally or alternatively, the microfluidic cartridge may support an alternate amplification process such as a different isothermal protocol, or a thermal cycling protocol. Such protocols could be polymerase chain reaction (PCR), ligase chain reaction, Q.beta. replicase, strand displacement assay, transcription mediated iso CR cycling probe technology, nucleic acid sequence-based amplification (NASBA) and cascade rolling circle amplification (CRCA),

**[0051]** In preferred embodiments the microfluidic cartridge is a single-use consumable, and the sample carrier is a single-use consumable. Such embodiments enable the control platform to accept a succession of microfluidic cartridges and to control the execution of a nucleic acid amplification process within each microfluidic cartridge, without the control platform itself coming into contact with potentially bio-hazardous material and thus without the need for the control platform to be located within a bio-safe containment facility. After completion of a test, the single-use microfluidic cartridge and sample carrier may be disposed of in a bio-safe manner. Thus, the microfluidic cartridge and sample carrier are preferably made of inexpensive materials and made to be of a small size to minimise the cost and waste associated with such single-use consumables. A small microfluidic cartridge providing an amplification chamber of small volume is further advantageous in minimising a volume of reagent(s) required for the nucleic acid amplification process, such that